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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/800,992	03/15/2004	Gary J. Beck	D-2804CON2	2049

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EXAMINER	
JAGOE, DONNA A	

ART UNIT	PAPER NUMBER
1614	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/800,992	BECK ET AL.	
	Examiner	Art Unit	
	Donna Jagoe	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 July 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *31-50* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *31-50* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *9/24/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 31-50 are pending in this application.

Applicants' arguments filed July 12, 2007 have been fully considered and they are deemed to be persuasive regarding previous rejections of record. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.

However, upon reconsideration, the following rejections and/or objections are newly applied. They constitute the complete set presently being applied to the instant application.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 31, 32 and 39, 41, 42 and 49 are rejected under 35 U.S.C. 102(b) as being anticipated by Lipari U.S. Patent No. 4,383,992

Lipari teaches an ophthalmic liquid composition comprising prednisolone acetate (column 1, lines 20-24) and a cyclodextrin derivative, beta cyclodextrin (see abstract), in a solution (column 1, line 59 to column 1, line 6). The composition increases partitioning of the steroid compound into the cornea with an increased therapeutic response (column 3, lines 65-68).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 31-50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lipari U.S. Patent No. 4,383,992. in view of Dziabo et al. U.S. Patent No. 5,424,078.

Lipari teaches an ophthalmic preparation comprising a beta cyclodextrin (see abstract) and prednisolone acetate (column 1, lines 20-24). Lipari lacks a teaching of a chlorine dioxide preservative and it does not teach an ophthalmically acceptable tonicity level, pH and buffer. Dziabo et al. teach an ophthalmic composition preserved with a stabilized chlorine dioxide preservative with an ophthalmically acceptable tonicity component and a buffer to maintain the pH of the ophthalmic formulation within the physiological range (see abstract). It would have been obvious to one of ordinary skill in the art at the time it was made to employ chloride dioxide as a preservative in an ophthalmic preparation motivated by the teaching of Dziabo et al. who employs stabilized chlorine dioxide as a preservative for ophthalmic preparations and teaches that ophthalmic preparations must have ophthalmically acceptable tonicity and buffer to maintain the pH of the ophthalmic formulation within the physiological range and Lipari who teaches that prednisolone acetate is made soluble for ophthalmic use by employing beta cyclodextrins. The method of preserving ophthalmic agents was recognized as part of the ordinary capabilities of one skilled in the art. One of ordinary skill in the art would have been capable of applying this known technique to a known composition that was ready for improvement and the results would have been predictable to one of ordinary skill in the art. The gap between the Lipari's ophthalmic composition of prednisolone acetate and cyclodextrin preserved with Dziabo et al.'s ophthalmic preservation system and the instant invention is simply not so great as to render the composition and method of use nonobvious to one reasonably skilled in the art.

Claim 40 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lipari U.S. Patent No. 4,383,992 and Loftsson U.S. 5,472,954 A.

Lipari teaches an ophthalmic liquid composition comprising prednisolone acetate (column 1, lines 20-24) and a cyclodextrin derivative, beta cyclodextrin (see abstract), in a solution (column 1, line 59 to column 1, line 6). Lipari does not teach the cyclodextrin sulfobutylether β-cyclodextrin. Loftsson et al. teach an ophthalmic composition (column 18, lines 8-12) comprising a cyclodextrin, such as the sulfobutyl ether of β cyclodextrin (column 6, line 60) and an anti-inflammatory steroid (column 19, lines 16-39), such as prednisolone (see table 10, column 28). Lipari teaches that beta cyclodextrin complexes the prednisolone acetate to form an ophthalmic solution. One of ordinary skill in the art could have substituted one known beta cyclodextrin for another known beta cyclodextrin and the results of the substitution would have been predictable. It would have been prima facie obvious to substitute one known method of solubilizing an insoluble prednisolone, such as prednisolone acetate for the other. Express suggestion to substitute one equivalent for another need not be present to render such substitution obvious. The prior art showed prednisolone acetate preserved with beta cyclodextrin. Therefore, it would have been obvious to one of ordinary skill in the art to substitute the sulfobutyl ether of β cyclodextrin taught in Loftsson for the ophthalmic preparation of prednisolone acetate for the predictable result of forming a solution for ophthalmic use.

Response to Arguments

Applicant's arguments with respect to claims 31-50 have been considered but are moot in view of the new ground(s) of rejection.

Applicants' reliance on the post filing date reference to allegedly provide evidence of surprising results is not persuasive. The determination of obviousness or nonobviousness must be based upon what was known in the art at the time the invention was made. See 35 U.S.C. § 103: "A patent may not be obtained...if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art".

The Declaration filed on July 12, 2007 under 37 CFR 1.131 has been considered but is ineffective to overcome the new rejections stated above.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Donna Jagoe whose telephone number is (571) 272-0576. The examiner can normally be reached on Monday through Friday from 8:00 A.M. - 4:30 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on (571) 272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Donna Jagoe
Patent Examiner
Art Unit 1614

November 13, 2007